Claim 38. A method for the treatment of skin wounds, fungal infections, eczema, bacterial infections in or on the skin and/or associated with skin wounds, athlete's foot, skin ulceration, burns, scalds, insect bites, allergic skin diseases, psoriasis, itching and pain, which comprises spraying on to skin in need of such treatment a composition according to Claim 22. --

REMARKS

Support for new Claims 22-38 can be found in original Claims 1 and 2 with respect to components (a) through (d).

Support for the proportions of the components (a) through (d) in new Claim 22 can be found at page 18, last paragraph of the present specification.

Support for the Markush group of substantially water insoluble film forming agents recited in new Claim 22 can be found at page 5, last paragraph of the specification.

Support for the feature of the skin patch disintegrating progressively over a 24-48 hour time period recited in new Claim 22 can be found at page 16, last paragraph of the present specification. Further, support for this amendment can be found at page 5, lines 23-26 of the present specification

New Claims 23-29 correspond to original Claims 3-9; new Claims 30-34 correspond to original Claims 11-15; and new Claims 35-38 correspond to original Claims 18-21.

Hence, new Claims 22-38 do not constitute new matter, and thus entry is requested.

Applicant would like to thank the Examiner for the opportunity to interview him with respect to the present

application. As indicated in the Interview Summary Record, the Examiner agreed that new Claims 22-38 presented herein obviate the outstanding rejections.

On page 2 of the Office Action, the Examiner maintains the rejection of Claims 1-3, 10-11, 13, 15-17 and 20-21 under 35 U.S.C. § 102(b) as being anticipated by Driggers et al.

Specifically, the Examiner notes Applicant's arguments that Driggers et al does not teach a water-soluble compound as recited in part (c) of Claim 1, i.e., Applicant alleges that the physiological active compounds taught by Driggers et al are soluble in an organic solvent and not water-soluble. However, the Examiner contends that Driggers et al teaches that the composition preferably includes water (see column 2, line 60), and therefore water-soluble medicaments are not excluded by the statement therein that medicaments are soluble in the solvent.

Further, the Examiner contends that Example 2 of Driggers et al discloses a composition comprising Lidocaine, the salt of which is water-soluble, as well as diethanolamine which is miscible with water (see column 5, line 45 to column 6, line 31).

For the following reasons, Applicant respectfully traverses the Examiner's rejection.

Driggers et al requires the use of polyvinylidene difluride, which gives rise to a bandage or glove which is tough and resilient (see col. 1, lines 41-42 and col. 6, lines 56-57 thereof).

On the other hand, the present invention is directed to porous film which progressively is able to disintegrate in a relatively short period of time.

The use of polyvinylidene difluride as taught in Driggers et al is clearly excluded from the present invention in view of the "consisting essentially of" language. This polymer is disadvantageous in the present invention since it would not allow for disintegration of the film, as required by the present invention.

In addition, insofar as Driggers et al refers to coatings containing physiologically active substances (col. 3, lines 3-6), these substances are taught to be soluble in solvent (col. 3, line 9), the organic solvent being described at col. 2, lines 38-40 thereof. It is noted in this regard that Lidocaine referred to at col. 6, lines 28-30 of Driggers et al is not water soluble. (Only salts of Lidocaine, such as the hydrochloride salt of Lidocaine are soluble in water.) This is in contrast to the compositions of new Claim 22, where the physiologically active ingredients are water-soluble.

Moreover, as noted by the Examiner, the compositions of Driggers et al preferably include water, which are in the form of the aqueous emulsion (see the Abstract and col. 3, lines 60-65).

On the other hand, in the present invention, water is not present.

While the present invention relates to the use of water-soluble compounds, this does not inherently mean that water is present.

The function of the water-soluble compound in the present invention is 2-fold. First, it is a physiologically active ingredient and second, it assists in degradation of the patch. That is, over the course of time, as the physiologically active ingredient is absorbed by the skin, holes form in the patch which provides for the porous nature of the patch (and allows the skin to breath), as well as promotes disintegration of the film. These features are not taught or suggested in Driggers et al.

Applicant have amended the claims to recite "consisting essentially of" to also exclude the presence of water, which is disadvantageous to creating the film of the present invention.

Moreover, in Driggers et al, plasticisers are added to the skin before application of the polymer dispersion (see column 5, lines 34-35). Driggers et al is thus, a 2 part composition, which is a burdensome and expensive to effect.

On the other hand, in the present invention, the plasticiser is a component of the claimed composition, rather than pre-applied to skin, as taught in Driggers et al

Furthermore, at column 4, Driggers et al teaches the composition is placed in an aerosol and dispersed in this manner.

On the other hand, the present invention is directed to a non-aerosol composition which is sprayable, i.e., a single application, not a two-step multi-component application, as taught in Driggers et al.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Driggers et al, and thus requests withdrawal of the Examiner's rejection.

On page 3 of the Office Action, the Examiner maintains the rejection of Claims 1-21 under 35 U.S.C. § 103 as being unpatentable over Tipton et al in view of Modak et al and Driggers et al.

Specifically, the Examiner notes Applicant's argument that Tipton et al does not teach water-soluble compounds. However, the Examiner contends that Tipton et al teaches that the biologically active ingredient may be miscible in the organic solvent or insoluble in the organic solvent, i.e., water-soluble (see column 8, lines 44-47). Further, the Examiner contends that Tipton et al teaches that release of the biologically active agent from the matrix can be varied by the solubility of the biologically active agent in water (see column 8, lines 62-65); and the use of water-soluble pore-forming agents (see column 7, lines 34-49). Hence, the Examiner concludes that Tipton et al teaches the use of water-soluble biologically active agents.

For the following reasons, Applicant respectfully traverses the Examiner's rejection.

Tipton et al relates to a <u>two-part</u> composition, wherein a thermoplastic polymer, with an optional bioactive agent in an organic solvent, is applied to skin, and then contacted with an aqueous based fluid to coagulate or solidify the film onto the human animal or tissue (see col. 3, line 57 to col. 4, line 9). The thermoplastic polymer of Tipton et al is substantially

insoluble in the aqueous fluid, giving rise to coagulation and film formation. This is entirely different from the present invention which is a one-step composition.

The mechanism of delivery of the water-soluble compound (e.g., peptide) in the present invention is taught at page 6, lines 19-34 of the present specification. There is no water in the film of the present invention, in distinct contrast to Tipton et al. However, when the film of the present invention comes into contact with moisture on the skin, the water-soluble material can leach out of the film.

Tipton et al therefore teaches compositions and methods which are very different from those claimed in the instant invention.

Moreover, one skilled in the art would not have been motivated to combine the teachings of Tipton et al with Driggers et al because the two-part compositions of each of these references are entirely different. That is, in Driggers et al, water is present in the polymeric composition which is applied to the skin after pre-application of a separate plasticiser/organic solvent composition. On the other hand, in Tipton et al, the thermoplastic polymer is dissolved in an organic solvent (see col. 3, lines 56 *et seq*) and thereafter, this composition is contacted with aqueous or body fluids so as to solidify and coagulate the polymer and to form the film.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Tipton et al or Driggers et al, and for the following reasons, it is equally

clear that Modak et al does not provide the deficiencies that exist therein.

Modak et al is entirely different from the present invention, as it relates to a gel. A gel is not sprayable. One skilled in the art would clearly not have been motivated to combine the gel teachings of Modak et al with Tipton et al and Driggers et al to achieve a non-aerosol sprayable skin patch composition, as claimed in the present invention. In any event, the combination of the teachings of Tipton et al and Modak et al does not give rise to the present invention.

Furthermore, Modak et al do not teach or suggest progressive disintegration over a 24 to 48 hour time period.

Applicant respectfully submits that the present invention is not taught or suggested in Tipton et al, alone or when combined with the teachings of Modak et al and Driggers et al, and in any event, the combination thereof can only be made in hindsight which is legally improper. Thus, Applicant requests withdrawal of the Examiner's rejection.

In view of the new claims, and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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A P P E N D I X

Marked-Up Version of Changes

IN THE CLAIMS:

Claims 1-21 are being cancelled.

New Claims 22-38 are being added.